

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE**

IN RE: Cases Transferred to TNMD from)	
In re: Taxotere (Docetaxel) Products Liability)	Judge Campbell
Litigation, MDL No. 16-2740 (LAED))	Magistrate Judge Holmes

SYLVIA JACKSON)	
)	
v.)	Case No. 3:23-cv-00553
)	
SANOFI-AVENTIS U.S. LLC and)	
SANOFI US SERVICES, INC.)	

FAYE BYRD)	
)	
v.)	Case No. 3:23-cv-01137
)	
SANOFI-AVENTIS U.S. LLC and)	
SANOFI US SERVICES, INC.)	

MEMORANDUM OPINION AND ORDER

Pending before the Court is a joint motion filed by Plaintiffs Sylvia Jackson and Faye Byrd (“Plaintiffs”) seeking leave to amend their respective complaints (*Jackson*, Docket No. 35) (*Byrd*, Docket No. 30),¹ to which Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc.

¹ Both Plaintiff Jackson’s motion and Plaintiff Byrd’s motion include an embedded supporting memorandum of law rather than a separately filed one as required by Local Rule 7.01(a)(2).

Further, on December 20, 2023, Plaintiff Byrd was instructed by the Clerk’s office to refile her motion for leave to amend the complaint because the document was “not in the correct numerical order.” (*Byrd*, Docket Entry Dated 12/20/2023.) Plaintiff Byrd failed to follow this instruction and did not refile her motion. Despite this failure, the Court will consider Plaintiff Byrd’s motion as it is presumably identical to the motion filed by Plaintiff Jackson, albeit with the pages in a different order. The Court cautions Plaintiff Byrd’s counsel to be attentive to all filings and to comply with the Clerk’s instructions in the future.

(“Defendants”) filed a response in opposition (*Jackson*, Docket No. 38)² (*Byrd*, Docket No. 32)³, and to which only Plaintiff Jackson filed a reply in support (*Jackson*, Docket No. 39).⁴

For the reasons set forth below, Plaintiffs’ joint motions for leave to amend their complaints (*Jackson*, Docket No. 35) (*Byrd*, Docket No. 30) are **DENIED**.

I. BACKGROUND

Plaintiffs’ cases were originally part of multidistrict litigation in the Eastern District of Louisiana, *In re Taxotere (Docetaxel) Products Liability Litigation MDL* (E.D. La., MDL No. 2740), and were both transferred to the Middle District of Tennessee “for individual treatment.” (Docket No. 8 at 1.)⁵ The MDL Court summarized Plaintiffs’ allegations as follows:

Plaintiffs in this MDL are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel, that

² In *Jackson*, Defendants originally filed a response that did not comply with Local Rule 5.01. (Docket No. 37.) After receiving a notice from the Clerk of Court (Docket Entry Dated January 4, 2024), Defendants refiled their response to comply with Local Rule 5.01. (Docket No. 38.) In their refiled response, Defendants also corrected a citation error in Footnote No. 7 and attached a revised Exhibit No. 6, both of which referenced the deposition transcript of David B. Madigan, Ph.D. *Compare* Docket No. 37 at 10 n.7 *with* Docket No. 38 at 10 n.7. *Compare* Docket No. 37-6 *with* Docket No. 38-6. No other changes appear to have been made to the response. The Court did not rely on the information included in Footnote No. 7 or Exhibit 6 to make its decision to deny Plaintiffs’ joint motion to amend.

³ Similarly, in *Byrd*, Defendants filed a new response to correct the same citation errors that are discussed *supra* note 2. *Compare* Docket No. 31 at 10 n.7 *with* Docket No. 32 at 10 n.7. *Compare* Docket No. 31-6 *with* Docket No. 32-6. No other changes appear to have been made to the response. The Court did not rely on the information included in Footnote No. 7 or Exhibit 6 to make its decision to deny Plaintiffs’ joint motion to amend.

⁴ Plaintiff Byrd did not file a reply in support of the joint motion to amend.

⁵ To make this memorandum opinion and order easier to read, the Court will only cite to a document’s location on the *Jackson* docket and will omit citation to the *Byrd* docket, unless it is necessary to cite to both. The parties have filed many, if not all, the same documents in both cases, so citation to the exact same document within two dockets is not necessary. Nevertheless, the Court reserves the right, as may be necessary based on further developments, to replace this memorandum opinion and order in the *Byrd* case solely to include noted docket citations in that case.

Plaintiffs were administered for the treatment of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, “Sanofi”). Plaintiffs allege that the drug caused permanent chemotherapy induced alopecia (“PCIA”). Plaintiffs assert several claims, including failure to warn, negligence, negligent misrepresentation, fraudulent misrepresentation, and fraudulent concealment.

(*Id.* at 1–2.) The MDL plaintiffs made their allegations in two complaints: (1) a “Master Complaint” applicable to all plaintiffs; and (2) a “Short Form Complaint” applicable to each individual plaintiff.

The operative Master Complaint is the Second Amended Master Complaint, which was filed on September 27, 2018. (Docket No. 6-26.) It sets forth general facts, allegations, and potential claims. It also defines Plaintiffs’ alleged injury, PCIA, as follows:

Unlike the temporary and reversible alopecia that ordinarily results from chemotherapy, Taxotere, Docefrez, Docetaxel Injection, and Docetaxel Injection Concentrate cause Permanent Chemotherapy Induced Alopecia, which is defined as an absence of or incomplete hair regrowth six months beyond the completion of chemotherapy.

(*Id.* at ¶ 181 (emphasis added).)

Plaintiff Byrd filed her Short Form Complaint on December 10, 2017 (*Byrd*, Docket No. 1) and Plaintiff Jackson filed hers on May 8, 2018 (*Jackson*, Docket No. 1). In their Short Form Complaints, Plaintiffs incorporated the operative Master Complaint by reference; included biographical information; identified defendants, a basis for jurisdiction, venue, brand products, dates of use of the products, and states in which the products were administered; described the “nature and extent of alleged injury (including duration, approximate date of onset (if known), and description of alleged injury)”; and chose counts in the Master Complaint that they sought to allege. (Docket No. 35-2 at 2–10.) Plaintiffs were also able to fill in a box in response to this prompt:

Plaintiff(s) may assert the additional theories and/or State Causes of Action against Defendant(s) identified by selecting “Other” and setting forth such claims below. If Plaintiff(s) includes additional theories of recovery, for example, Redhibition under Louisiana law or state consumer protection claims, the specific facts and allegations supporting additional theories must be pleaded by Plaintiff in sufficient detail as required by the applicable Federal Rules of Civil Procedure.

(*Id.* at 5, 10.) In response to that prompt, Plaintiffs stated as follows:

Plaintiff Byrd: Until recently, Plaintiff did not suspect, nor did she have reason to suspect, that wrongdoing had caused her injuries. In addition, Plaintiff did not have reason to suspect the tortious nature of the conduct causing the injuries, until recently and has filed the herein action well within the applicable statute of limitations period. Plaintiff had no knowledge of the wrongful conduct of the Defendants as set forth herein, nor did Plaintiff have access to the information regarding other injuries and complaints in the possession of Defendants. Additionally, Plaintiff was prevented from discovering this information sooner because Defendant misrepresented and continue to misrepresent to the public, to the medical profession and to Plaintiff that Taxotere is safe and free from serious side effects. Defendants have fraudulently concealed facts and information that could have led Plaintiff to an earlier discovery of potential causes of action.

Plaintiff Jackson: Extreme and Outrageous Conduct/Intentional Infliction of Emotional Distress against all Defendants; Punitive Damages.

(*Id.*)

After Plaintiffs filed their individual Short Form Complaints, the MDL plaintiffs sought leave to amend the Second Amended Master Complaint to “no longer define their injury as manifesting six months after chemotherapy.” (Docket No. 6-45 at 2.) Instead, the MDL plaintiffs sought to assert that “[t]here is no single definition for [PCIA] and the amount of time to establish permanent hair loss varies from patient to patient, including among Plaintiffs.” (*Id.*)

On December 12, 2019, the MDL Court denied the MDL plaintiffs’ request to amend, stating that “an amendment to the [Master] Complaint would be inappropriate at this time.” (*Id.* at 3.) In support of this denial, the MDL Court referenced Rule 15(a)(2) of the Federal Rules of Civil

Procedure⁶; noted that the parties had been operating under the original definition of PCIA since the original Master Complaint was filed in March 2017; noted that the MDL Court had used the original definition of PCIA to resolve discovery disputes and make summary judgment rulings; and noted that the MDL plaintiffs' own expert had adopted the original definition of PCIA in her expert report. (*Id.* at 2–4.) The MDL Court held that, if the MDL plaintiffs were granted leave to amend, Defendants would be “unduly prejudiced,” significant work of the parties and the MDL Court would be “negate[d],” and certain rulings would be “mooted.” (*Id.* at 4.) The MDL Court also thought it “apparent” that the main reason that the MDL plaintiffs sought to amend was to “save cases that are otherwise subject to dismissal for being filed too late.” (*Id.*) In short, the MDL Court denied the MDL plaintiffs' request to amend the definition of their injury.

Following this denial, the MDL Court issued Pretrial Order No. 105 (“PTO No. 105”) after the MDL plaintiffs began to amend their individual Short Form Complaints “in response to [the MDL] Court’s rulings on recent motions seeking to amend pleadings as they relate to statute of limitations.” (Docket No. 6-51 at 1.) PTO No. 105 gave the MDL plaintiffs an opportunity to amend their individual Short Form Complaints “to add factual allegations regarding particularized facts individual and specific to each Plaintiff’s medical care and treatment and/or that Plaintiff’s communications with medical professionals.” (*Id.*) This order required the MDL plaintiffs to continue to use the Short Form Complaint but stated that they should “tailor the form to correspond to each Plaintiff’s claims/allegations.” (*Id.* at 1–2.) The order set a deadline of 45 days for bellwether pool MDL plaintiffs and 180 days for non-bellwether pool MDL plaintiffs to amend their Short Form Complaints. (*Id.* at 2.) In a later order, the MDL Court cited to PTO No. 105 and stated, “All deadlines for Plaintiffs to amend their individual complaints without leave of court

⁶ Unless otherwise noted, all references to rules are to the Federal Rules of Civil Procedure.

have passed.” (Docket No. 8 at 4.) Neither Plaintiff Byrd nor Plaintiff Jackson amended their Short Form Complaint in response to PTO No. 105.

Plaintiffs now seek leave to amend their complaints to “allege case specific facts and exemplary damages” and to “set forth when [each Plaintiff] discovered the link between her injury of permanent hair loss and her use of Taxotere.” (Docket No. 35 at 6, 8.) Plaintiffs argue that the requested amendment is proper under Rule 15(a) because leave to amend should be freely given when justice so requires, and is proper under Rule 16(b)(4) because there is good cause for allowing the amendment.⁷ (*Id.* at 6–9, 10–12.) In support of their motion, Plaintiffs filed their proposed amended complaint, which is an amendment of the Second Amended Master Complaint rather than of each Plaintiff’s Short Form Complaint.⁸ (Docket No. 35-1.)

⁷ Plaintiffs also argue that “claim preclusion does not bar further amendments to Plaintiffs['] complaints.” (Docket No. 35 at 9.) In their response, Defendants state that they “do not argue” that claim preclusion bars further amendments. The Court agrees that claim preclusion does not apply in this instance, namely because this is the same lawsuit that Plaintiffs initiated in the MDL. *See Wheeler v. Dayton Police Dep’t*, 807 F.3d 764, 766 (6th Cir. 2015) (“Claim preclusion prevents parties from litigating matters that should have been advanced in an earlier suit.”) (quoting *Migra v. Warren City Sch. Dist. Bd. of Educ.*, 465 U.S. 75, 77 n. 1 (1984)) (cleaned up). For these reasons, the Court will not address Plaintiffs’ arguments regarding claim preclusion in any further detail.

⁸ Plaintiff Jackson filed a redlined version of her proposed amended complaint “in accordance with Eastern District of Tennessee Local Rule 15.1.” (Docket No. 35 at 2.) As Plaintiffs should know, this matter is pending in the *Middle* District of Tennessee and a different set of Local Rules apply. With respect to motions to amend pleadings, the Local Rules for this district require movants to “include as an appended exhibit” the proposed amended pleading which should “restate the entirety of the pleading with amendments incorporated.” Local R. 15.01(a)(1), (b). The Court reminds counsel for Plaintiff Jackson to familiarize themselves with and to comply with the Local Rules for this district. Failure to do so may result in the denial of future requests or other adverse consequences.

Plaintiff Byrd, on the other hand, filed a proposed amended complaint that does restate the entirety of the pleading with amendments incorporated. (*Byrd*, Docket No. 30-1.)

Defendants oppose Plaintiffs' motion. (Docket No. 38.) They argue that Plaintiffs' request to amend was previously denied by the MDL Court, that Plaintiffs previously had an opportunity to amend but failed to do so, and that amendment would be futile. (*Id.* at 1–2.) As discussed below, the Court largely agrees with Defendants that Plaintiffs' request to amend should be denied.

II. LEGAL STANDARDS

Although the Sixth Circuit has not directly addressed whether a motion to amend is a dispositive or non-dispositive motion, most district courts in the Sixth Circuit, including this court, consider an order on a motion to amend to be non-dispositive. *See, e.g., Gentry v. The Tennessee Bd. of Jud. Conduct*, No. 3:17-cv-00020, 2017 WL 2362494, at *1 (M.D. Tenn. May 31, 2017) (“Courts have uniformly held that motions to amend complaints are non-dispositive matters that may be determined by the magistrate judge and reviewed under the clearly erroneous or contrary to law standard of review . . .”) (citations omitted); *Chinn v. Jenkins*, No. 3:02-cv-00512, 2017 WL 1177610, at *2 (S.D. Ohio Mar. 31, 2017) (order denying motion to amend is not dispositive); *Young v. Jackson*, No. 12-cv-12751, 2014 WL 4272768, at *1 (E.D. Mich. Aug. 29, 2014) (“A denial of a motion to amend is a non-dispositive order.”); *Hira v. New York Life Ins. Co.*, No. 3:12-CV-00373, 2014 WL 2177799, at *1–2 (E.D. Tenn. May 23, 2014) (magistrate judge’s order on motion to amend was appropriate and within his authority because motion to amend is non-dispositive); *United States v. Hunter*, Nos. 3:06-cr-00061, 3:12-cv-00302, 2013 WL 5820251, at *1 (S.D. Ohio Oct. 29, 2013) (stating that a magistrate judge’s orders denying petitioner’s motions to amend a petition pursuant to 28 U.S.C. § 2855 were non-dispositive). *See also Elliott v. First Fed. Comm. Bank of Bucyrus*, 821 F. App’x 406, 412–13 (6th Cir. 2020) (referring generally to motion for leave to amend as non-dispositive motion).

Typically, motions for leave to amend are considered under the deferential standard of Rule 15(a)(2), which directs that the court “should freely give leave when justice so requires.” Fed. R. Civ. P. 15(a)(2). Under that standard, the district court has substantial discretion and may deny a motion for leave “based on undue delay, bad faith or dilatory motive or futility of amendment.” *Pedreira v. Ky. Baptist Homes for Children*, 579 F.3d 722, 729 (6th Cir. 2009). However, notwithstanding the language in Rule 15(a)(2) that leave to amend shall be freely granted, “a party must act with due diligence if it intends to take advantage of the Rule's liberality.” *United States v. Midwest Suspension & Brake*, 49 F.3d 1197, 1202 (6th Cir. 1995) (citing *Troxel Mfg. Co. v. Schwinn Bicycle Co.*, 489 F.2d 968 (6th Cir. 1973)). “The longer the period of an unexplained delay, the less will be required of the nonmoving party in terms of a showing of prejudice.” *Phelps v. McClellan*, 30 F.3d 658, 662 (6th Cir. 1994) (quoting *Evans v. Syracuse City Sch. Dist.*, 704 F.2d 44, 47 (2d Cir. 1983)) (internal quotation marks omitted).

Moreover, “a different standard applies when a proposed amendment is so late that it would require the modification of a Rule 16 scheduling order.” *Korn v. Paul Revere Life Ins. Co.*, 382 F. App'x 443, 449 (6th Cir. 2010) (citing *Leary v. Daeschner*, 349 F.3d 888, 904 (6th Cir. 2003)). Rule 16(b) provides that “[a] schedule may be modified only for good cause and with the judge's consent.” Fed. R. Civ. P. 16(b)(4). “Despite the lenient standard of Fed. R. Civ. P. 15(a) with regard to amending the pleadings, a court may deny leave to amend the pleadings after the deadline set in the scheduling order where the moving party has failed to establish good cause.” *J.H. by Harris v. Williamson Cty., Tennessee*, Case No. 3:14-cv-02356, 2017 WL 11476336, at *2 (M.D. Tenn. May 18, 2017) (citing *Leary*, 349 F.3d at 906)). The purpose of this requirement, and its heightened standard, is “to ensure that at some point both the parties and the pleadings will be fixed,” subject only to modification upon a showing of good cause. *Leary v. Daeschner*, 349 F.3d

888, 906 (6th Cir. 2003), *quoting* Fed. R. Civ. P. 16, 1983 advisory committee's notes (internal quotation marks omitted); *see also Pizella v. E.L. Thompson Assocs., LLC*, Case No. 3:18-cv-00023, 2019 WL 10960444, at *1 (M.D. Tenn. Aug. 22, 2019); *Stewart v. King*, Case No. 3:09-cv-00021, 2011 WL 237678, at *4 (M.D. Tenn. Jan. 24, 2011) (citing *Leffew v. Ford Motor Co.*, 258 F. App'x 772, 777 (6th Cir. 2007)).

The “good cause” requirement is “a threshold that requires late-moving litigants to show that despite their diligence they could not meet the original deadline.” *Shane v. Bunzl Dist. USA, Inc.*, 275 F. App'x 535, 536 (6th Cir. 2008) (quoting *Leary*, 349 F.3d at 907) (cleaned up). Courts determine good cause by measuring the movant’s “diligence in attempting to meet the case management order’s requirements.” *Inge v. Rock Fin. Corp.*, 281 F.3d 613, 625–26 (6th Cir. 2002). Put another way, in determining whether good cause exists, the “overarching inquiry” is whether the moving party was diligent in attempting to meet the court’s deadlines. *Marie v. Am. Red. Cross*, 771 F.3d 344, 366 (6th Cir. 2014) (quoting *Bentkowski v. Scene Magazine*, 637 F.3d 689, 696 (6th Cir. 2011)).

Further, in considering “good cause,” the court must also take into account – as one “consideration that informs” the analysis – whether the non-movant would be prejudiced by the amendment and the modification of the scheduling order. *Korn*, 382 F. App'x at 450. Even if no prejudice is evident, a movant must still explain why the amendment was not sought “at a time that would not have required a modification of the scheduling order.” *Korn*, 382 F. App'x at 450. “Where the [moving party’s] explanation for the delay is simply insufficient or not credible, it is appropriate for the court to deny the motion for leave to amend.” *Stewart v. King*, No. 3:09-cv-21, 2011 WL 237678, at *5 (M.D. Tenn. Jan. 24, 2011) (citing *Korn v. Paul Revere Life Ins. Co.*, 382 F. App'x 443, 449 (6th Cir. 2010); *Commerce Benefits Grp. v. McKesson Corp.*, 326 F. App'x

369, 376 (6th Cir. 2009)). Only if the movant establishes “good cause” for an extension of the amendment deadline does the court proceed to the more permissive Rule 15(a)(2) analysis. *Commerce Benefits*, 326 F. App’x at 376.

III. ANALYSIS

In their motion, Plaintiffs set forth four main arguments in support of amending their complaints: (1) no deadline to amend has been put in place, though if one had been, there is good cause to modify the deadline and allow amendment under Rule 16(b)(4); (2) Plaintiffs’ request to amend is not unduly delayed under Rule 15(a)(2) because there have been neither case-specific nor general MDL deadlines to amend; (3) Defendants will not be unfairly prejudiced under Rule 15(a)(2) by the amendments; and (4) the amendments are not futile under Rule 15(a)(2). (Docket No. 35 at 6–9.) In response, Defendants argue that amendment should not be permitted because Plaintiffs are requesting to make an amendment that is identical to one that the MDL Court previously denied; Plaintiffs were previously provided with an opportunity to amend but failed to do so; and amendment would be futile. (Docket No. 38 at 1–2.) As explained below, the Court finds that leave to amend should not be permitted under either Rule 16(b)(4) or Rule 15(a)(2) because Plaintiffs have not demonstrated good cause to amend the applicable scheduling order; Plaintiffs’ request is unduly delayed; and Plaintiffs’ request is prejudicial to Defendant.⁹

⁹ In their motion, Plaintiffs argue that their request is “not made in bad faith or with a dilatory motive.” (Docket No. 35 at 7.) Defendants do not address this contention in their response. (Docket No. 38.) The Court finds that Plaintiffs have not acted in bad faith when seeking leave to amend their complaints, but the Court will not analyze this prong of the Rule 15(a)(2) analysis because it is not in controversy.

1. Plaintiffs Have Not Demonstrated Good Cause to Modify the MDL Court's Scheduling Order.

Plaintiffs argue that there is no need to demonstrate “good cause” to modify a scheduling order because there has never been a case-specific deadline or a general MDL deadline that would need to be modified under Rule 16(b)(4). Defendants disagree and argue that the MDL Court set deadlines by which Plaintiffs were required to amend their complaints, but that Plaintiffs failed to meet these deadlines.

In their joint motion, Plaintiffs rely on the fact that this Court has not set a deadline to amend in these remanded matters.¹⁰ Whether this Court set a deadline for Plaintiffs to amend their complaints is not, however, the pertinent question. Recognizing the potential issues regarding amendments following remand, this Court required the parties to file additional briefing on whether Plaintiffs could be given leave to amend at all at this juncture. (Docket No. 32 at 8, 14.) That is the threshold question.

And to answer that question, this Court must consider the effect of the MDL Court's prior orders, specifically the MDL Court's PTO No. 105. As detailed above, PTO No. 105 gave the MDL plaintiffs an opportunity to amend their individual Short Form Complaints “to add factual allegations regarding particularized facts individual and specific to each Plaintiff's medical care and treatment and/or that Plaintiff's communications with medical professionals.” (Docket No. 6-51 at 1.) This order set a schedule for the MDL plaintiffs to file their motions to amend.

¹⁰ Plaintiffs argue that their request to amend is “timely” and “consistent” with requests made by other plaintiffs whose cases have been remanded from MDLs. (Docket No. 354 at 7.) As discussed in more detail below, other home courts have construed PTO No. 105 as setting a deadline by which the MDL Plaintiffs were required to amend their complaints.

Accordingly, this Court finds that PTO No. 105 is a scheduling order under Rule 16 and, therefore, Plaintiffs must demonstrate “good cause” to revise the deadlines in that order.¹¹

Plaintiffs argue that PTO No. 105 did not limit their ability to “mak[e] amendments relevant to the statute of limitations.” (Docket No. 35 at 11.) Instead, they believe that PTO No. 105 was narrow in scope and only set a deadline for amendments related to facts specific to each Plaintiff’s “medical care and treatment” and “communications with medical professionals.” (*Id.*) As a result, Plaintiffs ask this Court to reconsider the MDL Court’s order. (*Id.*)

This Court will not disturb the MDL Court’s ruling in PTO No. 105. “Under the doctrine of the law of the case, a decision on an issue made by a court at one stage of a case should be given effect in successive stages of the same litigation.” *United States v. Todd*, 920 F.2d 399, 403 (6th Cir. 1990) (citing *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988)). “This doctrine applies with equal vigor to the decisions of a coordinate court in the same case and to a court’s own decisions.” *Id.* (citing *Christianson*, 486 U.S. at 816). Extraordinary circumstances may warrant revisiting a previously decided issue if the coordinate court’s ruling was “clearly erroneous or would work a manifest injustice.” *Holloway v. Brush*, 220 F.3d 767, 785 (6th Cir. 2000) (quoting *Christianson*, 486 U.S. at 817). Further, treating issues resolved in by the MDL court as the law of the case promotes judicial efficiency by coordinating and consolidating pretrial proceedings. *Cuter v. Ethicon, Inc.*, No. 5:19-443-DCR, 2020 WL 2060342, at *2 (E.D. Ky. Apr.

¹¹ In their response, Defendants argue that Rule 16 does not apply because Plaintiffs are not seeking to amend a “pretrial scheduling order.” (Docket No. 38 at 11 n.9.) The Court disagrees. As discussed above, PTO No. 105 is a scheduling order under Rule 16 that set a date by which Plaintiffs had to file a motion for leave to amend their Short Form Complaints. That date has passed, so Plaintiffs must demonstrate “good cause” to modify the deadline. *See Leary v. Daeschner*, 349 F.3d 888, 906 (6th Cir. 2003). However, even if Rule 16 did not apply, the Court finds that Plaintiffs have failed to demonstrate that leave to amend should be granted under Rule 15, which is discussed in detail below.

29, 2020) (citing *Mathews v. Novartis Pharms. Corp.*, No. 3:12-cv-314, 2013 WL 5780415, at *16 (S.D. Ohio Oct. 25, 2013)).

Here, Plaintiffs have failed to demonstrate that the MDL Court's ruling in PTO No. 105 was either "clearly erroneous" or would "work a manifest injustice." Plaintiffs make a brief argument that the MDL Court did not conduct the "necessary analysis" under Rule 15 regarding whether leave was to be freely given. (Docket No. 35 at 11.) However, Plaintiffs offer no authority for their contention that the MDL Court was required to analyze Rule 15 when issuing PTO No. 105. Courts routinely issue scheduling orders under Rule 16 that set deadlines for motions for leave to amend without substantive analysis of the Rule 15 factors. Accordingly, and in the absence of contrary authority, this Court finds little merit to Plaintiffs' argument that the MDL Court's failure to analyze Rule 15 in setting an amendment deadline in PTO No. 105 was "clearly erroneous."

Plaintiffs also ignore the fact that PTO No. 105 *permitted* the MDL plaintiffs to amend their Short Form Complaints. (Docket No. 6-51 at 1.) The MDL Court entered PTO No. 105 to provide the MDL plaintiffs with guidelines as they began to amend their Short Form Complaints in response to the MDL Court's "rulings on recent motions seeking to amend pleadings as they relate to statute of limitations." (*Id.*) In those "rulings on recent motions," the MDL Court did, indeed, consider Rule 15 when it denied the MDL plaintiffs' request to amend the Master Complaint. (Docket No. 6-45 at 2–3.) For these reasons, the Court will not disturb the MDL Court's orders in PTO No. 105.

Instead, the Court must consider whether PTO No. 105 contained deadlines that would govern Plaintiffs' current request to amend their complaints. Plaintiffs state that they wish to amend their complaints to make allegations related to: (1) general case specific facts, (2)

exemplary damages, and (3) a discovery date. (Docket No. 35 at 6, 8.) However, a review of Plaintiffs’ proposed amended complaints shows that Plaintiffs seek to make far more changes than just these. Importantly, Plaintiffs seek to revise the MDL-approved definition of PCIA from “an absence of or incomplete hair regrowth six months beyond the completion of chemotherapy” (Docket No. 6-26 at ¶ 181) to the following:

There is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of or time to establish permanent hair loss varies from patient to patient. The scientific literature has variously referred to Permanent Chemotherapy Induced Alopecia as occurring between six to twenty-four months following chemotherapy treatment.

(Docket No. 35-1 at ¶ 102.) The MDL Court explicitly rejected the MDL plaintiffs’ previous request to make this exact amendment:

The proposed amended complaint alleges that “[t]here is no single definition for Permanent Chemotherapy Induced Alopecia and the amount of time to establish permanent hair loss varies from patient to patient, including among Plaintiffs.” . . . Presumably, Plaintiffs made an informed decision to define their injury the way they originally did. The Court will not allow Plaintiffs at this point in the MDL to backtrack on that decision. Accordingly, the Court denies Plaintiffs’ Motion.

(Docket No. 6-45 at 2, 5.)

Not only has this exact amendment been disallowed previously, but the MDL Court has itself stated that “[a]ll deadlines for Plaintiffs to amend their individual complaints without leave of court have passed.” (Docket No. 8 at 21 (citing PTO No. 105, Docket No. 6-51).) Other courts that have received transferred cases from the MDL Court back to the home court have also construed PTO No. 105 to set a deadline by which the MDL Plaintiffs could amend their complaints. *See, e.g., Maxwell v. Sanofi-Aventis U.S. LLC*, No. 2:23-CV-696-ACA, 2023 WL 7115575 (N.D. Ala. Oct. 27, 2023) (“When the judicial panel presiding over the multidistrict litigation remanded this case, the panel advised this court that the panel had directed all plaintiffs

to amend their short-form complaints to include plaintiff-specific allegations for the fraud claims. . . . The deadline to plead those allegations has expired . . . ”).¹²

Based on the MDL Court’s own description of the deadline to amend and consistent with the sound construction and application of PTO No. 105 by other home courts, this Court finds that the deadline for the amendments that Plaintiffs seek to make – (1) general case specific facts, (2) exemplary damages, and (3) a discovery date – has passed. First, PTO No. 105 set an explicit deadline for MDL plaintiffs to amend their Short Form Complaints to add “particularized facts individual and specific to each Plaintiff’s medical care and treatment.” (Docket No. 6-51 at 1.) Second, the Short Form Complaint itself allowed Plaintiffs to allege exemplary – or punitive – damages, which Plaintiff Jackson did. (Docket No. 35-2 at 6.) Further, the Second Amended Master Complaint seeks “punitive or exemplary damages” already. (Docket No. 6-26 at ¶ 320.) Finally, the Short Form Complaint also allowed Plaintiffs to allege facts related to their discovery of their injuries, and PTO No. 105 also explicitly provided a deadline by which Plaintiffs could assert such allegations.

In addition, although Plaintiffs state that “many short form complaint amendments have been accomplished after the deadline established by PTO 105” (Docket No. 35 at 11), they give no explicit examples and provide no explicit citations to support this assertion. Further, the amendments that Plaintiffs seek to make are to the Second Amended Master Complaint, and not

¹² Defendants provided other examples wherein district courts found that the MDL Court’s PTO No. 105 set a deadline for amendments, which has passed. *See* Docket No. 38-7 at 2 n.1 (Aug. 1, 2023 scheduling order from S.D. Fla. finding that “Plaintiff has already been afforded the opportunity to amend her complaint within the multidistrict litigation and the deadline set by that court to amend the pleadings has long since passed”); Docket No. 40-1 at 2 (Jan. 12, 2024 docket text from M.D. Fla. denying a plaintiff’s motion to amend and finding that “the requested amendment would unduly prejudice Defendants and would undermine the rulings already made by the MDL Court”).

their individual Short Form Complaints. Accordingly, any prior amendments to Short Form Complaints by other MDL plaintiffs would be much less relevant. The Court therefore gives no weight to this argument. For all these reasons, the Court finds that PTO No. 105 is a scheduling order, the modification of which requires “good cause” under Rule 16(b)(4).

To make a showing of good cause, Plaintiffs must demonstrate that “despite their diligence they could not meet the original deadline.” *Leary*, 349 F.3d at 907. With respect to their diligence, Plaintiffs state:

Pretrial Order No. 105 was entered by the MDL Court, the Order was expressly titled: “Short Form Complaint Allegations and Amendments – Statute of Limitations Order.” For the purposes of making amendments relevant to the statute of limitations, PTO 105 limited the substance of what Plaintiffs would be granted leave to file to: “factual allegations regarding particularized facts individual and specific to each Plaintiff’s medical care and treatment and/or that Plaintiff’s communications with medical professionals.” PTO 105 impermissibly limited the ability of Plaintiffs to allege case specific facts without conducting the necessary analysis of whether to grant leave under Rule 15. Under Rule 54(b) this Court has vast discretion to reconsider the interlocutory ruling in PTO 105 that limited Plaintiffs’ ability to seek leave to amend under Rule 15. Fed. R. Civ. P. 54(b).

(Docket No. 35 at 11.) The Court finds this argument to be conflated and confusing. As discussed above, the Court finds no grounds to reconsider PTO No. 105 and finds that Plaintiffs have failed to establish that the MDL Court was required to analyze Rule 15 when issuing PTO No. 105.

The Court supposes that Plaintiffs are trying to argue that PTO No. 105 was narrow and applied only to amendments regarding their “medical care and treatment” and their “communications with medical professionals.” However, as discussed above, the MDL Court and several other courts have interpreted PTO No. 105 as containing broad deadlines “for Plaintiffs to amend their individual complaints” and have characterized those deadlines as now passed. (Docket No. 8 at 21.) Plaintiffs did not move to amend within the time frame set by the MDL Court and have made no argument as to why they could not have done so, except to say that they thought this

deadline did not apply to them. The Court is not persuaded. For these reasons, the Court finds that Plaintiffs have failed to demonstrate “good cause” to modify PTO No. 105’s deadline to file motions to amend their complaints. Accordingly, leave to amend must be denied.

2. Plaintiffs’ Request to Amend Is Unduly Delayed.

Even if leave to amend was not precluded by Rule 16(b)(4) under the circumstances here – which it is – Plaintiffs’ request fares no better under Rule 15(a)(2).¹³ Denial of a motion to amend is appropriate where there is undue delay, among other factors. *See Morse v. McWhorter*, 290 F.3d 795, 800 (6th Cir. 2002) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)). “Although Rule 15(a) indicates that leave to amend shall be freely granted, a party must act with due diligence if it intends to take advantage of the Rule’s liberality.” *United States v. Midwest Suspension & Brake*, 49 F.3d 1197, 1202 (6th Cir. 1995).

Here, the Court finds that leave to amend should be denied because Plaintiffs’ amendments are unduly delayed. Plaintiffs argue that their request is not unduly delayed because there have been neither case-specific nor general MDL deadlines that would either preclude Plaintiffs from amending their complaints now that the case has been remanded to this Court or render their current request to amend delayed, let alone unduly delayed. However, as discussed above, the Court finds that the MDL Court imposed a deadline to file motions to amend, which Plaintiffs failed to meet. For many of the same reasons that Plaintiffs failed to demonstrate “good cause”

¹³ While other courts may have allowed other plaintiffs to move for leave to amend after the cases were remanded from an MDL, those courts still engaged in an analysis under Rule 15(a)(2) to determine whether leave to amend was warranted. *See Bratcher v. Biomet Orthopedics, LLC*, No. 19-cv-4015-SAC-TJJ, 2019 WL 2342976, at *2 (D. Kan. Jun. 3, 2019) (discussing analysis under Rule 15(a)(2)); *Mars v. Novartis Pharms. Corp.*, No. 11-2555-RDR, 2012 WL 1288729, at *1 (D. Kan. Apr. 16, 2012) (same); *Stevens v. Novartis Pharms. Corp.*, No. 12-1414-EFM, 2013 WL 11332737, at *1 (D. Kan. Jul 11, 2013) (same).

under Rule 16(b)(4), Plaintiffs have also failed to demonstrate that their amendments are not unduly delayed.

In their proposed amended complaints, Plaintiffs seek to “allege case specific facts and exemplary damages” and to “set forth when [each Plaintiff] discovered the link between her injury of permanent hair loss and her use of Taxotere.” (Docket No. 35 at 6, 8.) For example, Plaintiffs seek to amend to allege that each Plaintiff “did not suspect, nor did she have reason to suspect, that Taxotere prevented hair regrowth or the tortious nature of Sanofi’s conduct causing her injuries until 2017.” (Docket No. 35-1 at ¶ 137.) However, Plaintiffs offer no rationale to explain why they could not have amended their complaints at an earlier point in time to include these allegations about a discovery they made either before or shortly after they each filed their Short Form Complaints.

During the MDL proceedings, neither Plaintiff Jackson nor Plaintiff Byrd amended their Short Form Complaints after PTO No. 105 was entered, despite its clear permission to do so. Nor did they seek leave to amend at a later time despite the MDL Court setting forth a procedure for just that request. (Docket No. 6-60 (“If, after following the conferral process set forth in PTO 105, ¶ 3, a Plaintiff seeks leaves to amend which is opposed by Defendants on the basis that the allegations Plaintiff seeks to include in a proposed SFC are inconsistent with PTO 105 or this Court’s Orders addressing motions to amend SFCs, including any allegations that have previously been disallowed by the Court, the Defendant may place the case on a call docket . . .”).)¹⁴

¹⁴ Plaintiffs reference this document in their reply and argue that it includes an agreement wherein “Plaintiff[s] agreed not to include new allegation[s] or amendments in [their] Short Form Complaint, and Defendant agreed not to assert waiver of any Plaintiff[s]’ request[s] to amend once cases were remanded to forum courts.” (Docket No. 39 at 3.) The Court does not find it necessary to make a ruling on the scope of this stipulation, but a plain reading indicates that the stipulation is narrower than Plaintiffs describe.

Plaintiffs argue that the amendments they seek to make are not unduly delayed because this joint motion is timely. The Court agrees with Plaintiffs that the presently pending joint motion is timely, but the operative question is whether Plaintiffs were unable to meet the *original* deadline set by PTO No. 105 despite their best efforts. Plaintiffs have provided no other arguments to explain why they did not move to amend their complaints within the time frame contained within PTO No. 105, which was entered in May 2020, or in compliance with the stipulation regarding PTO No. 105, which was entered in October 2020. Instead, their explanations for their delay are “simply insufficient or not credible.” *Stewart*, 2011 WL 237678 at *5. For these reasons and for the reasons discussed in this Court’s analysis regarding Rule 16(b)(4), the Court finds that Plaintiffs’ request to amend is unduly delayed.

3. Plaintiffs’ Request to Amend Is Unfairly Prejudicial to Defendants.

Although the Court finds that Plaintiffs’ request to amend is unduly delayed, undue delay alone, without significant prejudice to the defendant, is an insufficient reason to deny a motion to amend under Rule 15(a)(2). *Moore v. City of Paducah*, 790 F.2d 557, 562 (6th Cir. 1986) (holding it was abuse of discretion to deny amendment because of undue delay where there was only “relatively light prejudice” to defendant); *see Wade v. Knoxville Utilities Bd.*, 259 F.3d 452, 459 (6th Cir. 2001) (“[D]elay alone was not sufficient reason to deny the amendment . . .”). However, “[t]he longer the period of an unexplained delay, the less will be required of the nonmoving party in terms of a showing of prejudice.” *Church Joint Venture, LP v. Blasingame*, 947 F.3d 925, 934 (6th Cir. 2020) (quoting *Pittman v. Experian Info. Sols., Inc.*, 901 F.3d 619, 641 (6th Cir. 2018)).

To prevail in defeating a motion to amend, “the party opposing . . . must make some significant showing of prejudice.” *Security Ins. Co. of Hartford v. Tucker & Assoc.*, 64 F.3d 1001, 1009 (6th Cir. 1995). The standard for undue prejudice is whether the amendment would require

the opposing party to expend significant additional resources to conduct discovery and prepare for trial or significantly delay resolution of the dispute. *Phelps v. McClellan*, 30 F.3d 658, 663 (6th Cir. 1994).

To demonstrate prejudice, Defendants argue that Plaintiffs’ requested amendments would alter the definition of their injury in harmful ways. Defendants contend that “general case discovery, general expert discovery, dispositive motion rulings, pre-trial rulings, and trial verdicts emanating from the MDL have all been framed by the allegations made in Plaintiffs’ Second Amended Master Complaint, including the six-month injury definition.” (Docket No. 38 at 10.) Accordingly, Defendants assert that much of the case work that has already been completed would have to be done anew if Plaintiffs were permitted to change their injury definition. (*Id.*) They contend that “general expert discovery would have to be reopened, new expert analyses conducted, general causation and Daubert briefing redone, and trial preservation testimony retaken.” (*Id.*)

Defendants also point to the MDL Court’s prior rulings as evidence of prejudice. They assert that the MDL Court established an injury definition in 2017 and used that definition consistently to decide discovery disputes and dispositive motions; accordingly, a revision to that definition would “negate” the MDL Court’s prior work. In particular, Defendants point to the MDL Court’s 2019 decision to deny the MDL plaintiffs’ motion for leave to amend the Master Complaint. (Docket No. 6-45.) As detailed above, when the MDL Court denied that request, it noted that the parties had been operating under the original definition of PCIA since 2017; that the MDL Court had used the original definition of PCIA to resolve discovery disputes and make summary judgment rulings; and that the MDL plaintiffs’ own expert had adopted the original definition of PCIA in her expert report. (*Id.* at 2–4.) The MDL Court held that, if the MDL plaintiffs were granted leave to amend, Defendants would be “unduly prejudiced,” significant work of the

parties and the MDL Court would be “negate[d],” and certain rulings would be “mooted.” (*Id.* at 4.)

Plaintiffs argue that the amendments would not result in any “unfair prejudice” to Defendants because there would be no need to “undo” the parties’ prior work. (Docket No. 39 at 1.) Plaintiffs contend that “discovery is what it is” and prior “general discovery” should not be disturbed. (*Id.* at 1–2.) They also assert that Defendants failed to identify what discovery would need to be redone. (*Id.* at 2.) This argument misses the mark.

While Plaintiffs may see no need to “undo” or “redo” discovery if the definition of their injury were to change, Defendants make persuasive arguments in support of their contrary position. (Docket No. 38 at 10.) Further, the MDL Court also disagreed when faced with this same question. (Docket No. 6-45 at 4 (“If the Court were to allow Plaintiffs to amend at this late stage, this would negate a significant amount of the work that has been done in this MDL. Defendants would undoubtedly want to revise certain expert reports and conduct supplemental depositions, and certain rulings from the Court would be mooted.”).) Just as the MDL Court found that allowing the MDL plaintiffs to amend the injury definition would prejudice Defendants, this Court also finds that allowing Plaintiffs to amend the injury definition would likewise prejudice Defendants. As Defendants described, the amendment would require Defendants to expend significant additional resources to conduct discovery and prepare for trial. *See Phelps*, 30 F.3d at 663.

In addition, Plaintiffs argue that Defendants will not be prejudiced by the amendments because these changes will “clarify” when Plaintiffs knew of the link between their use of Taxotere and their injury. (Docket No. 35 at 8.) They contend that these new allegations are “consistent with Plaintiff[s]’ testimony in this matter and do[] not create prejudice or give rise to a new cause of action.” (*Id.*) They argue that there is “nothing ‘wrong’ with . . . requesting the defendant’s statute

of limitations defense be determined by analysis of all case-specific relevant facts, rather than by the mechanistic application of a master pleading . . . designed to facilitate pleading and discovery in multi-district litigation.” (Docket No. 39 at 2.)

While there may be nothing “wrong” with Plaintiffs’ preferred approach, allowing Plaintiffs to amend at this stage would nullify the work of the MDL Court. As the MDL Court stated, the Judicial Panel on Multidistrict Litigation created MDL 2740 to “eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel, and the judiciary.” (Docket No. 8 at 1.) As part of its duties, the MDL Court addressed numerous statutes of limitations issues. (*Id.* at 23.) Accordingly, for this Court to rescind the MDL Court’s prior rulings related to amendments and the statute of limitations – without a proper showing by Plaintiffs that those rulings were either “clearly erroneous or would work a manifest injustice,” *Holloway*, 220 F.3d at 785 – would defeat the purpose of consolidated MDL litigation, which is to “serve the convenience of the parties and witnesses and promote the just and efficient conduct of . . . litigation.” *In re Taxotere (Docetaxel) Products Liab. Litigation*, 220 F.Supp.3d 1360, 1361 (J.P.M.L. 2016).

Finally, Plaintiffs argue that that they are the parties who will be prejudiced if amendment is not permitted. (Docket No. 35 at 8.) As an initial matter, prejudice to the moving party if the motion to amend is denied is not a specific factor in determining whether leave should be permitted. Rather, the Court finds that the language of Rule 15 directing courts to freely permit amendments “when justice so requires” contemplates a general consideration of the impact of the outcome on the moving party. Nevertheless, the Court finds little merit in Plaintiffs’ substantive arguments. They assert that their amendments should be permitted because issues related to the statute of limitations should be “determined by the actual record and actual science regarding

[their] cellular level injury.” (Docket No. 39 at 1.) In other words, Plaintiffs believe that this Court should ignore the MDL Court’s 2019 decision to deny the MDL plaintiffs’ motion for leave to amend, and instead allow Plaintiffs to amend their complaints to alter the definition of PCIA, a task that this Court finds no basis to undertake. For the reasons explained above, this Court will not disturb the MDL Court’s denial of a prior motion for leave to amend the Master Complaint, nor will this Court disturb the MDL Court’s PTO No. 105, which set forth a deadline by which MDL plaintiffs could amend their Short Form Complaints.

For these reasons, the Court finds that Defendant has made an adequate and significant showing of prejudice under Rule 15(a)(2). *See Moore*, 790 F.2d at 562; *Security Ins. Co. of Hartford*, 64 F.3d at 1009.¹⁵

4. The Court Need Not Determine Whether the Requested Amendments Are Futile.

A proposed amendment is futile when it would not survive a motion to dismiss under Rule 12(b)(6). The Sixth Circuit has made it clear that a futility analysis under Rule 15(a)(2) is equivalent to that undertaken in consideration of a dispositive motion. *Rose v. Hartford Underwriters Ins. Co.*, 203 F.3d 417, 421 (6th Cir. 2000). In connection with a motion to amend, the “Court’s role is to evaluate only whether the futility of an amendment is so obvious that it should be disallowed.” *Oro Capital Advisors, LLC v. Borro Construction Co., LLC*, Nos. 2:19-cv-5087, 2:20-cv-4894, 2022 WL 3026862, at *10 (S.D. Ohio Aug. 1, 2022) (internal citations omitted).

¹⁵ This conclusion is in line with recent orders from other district courts finding that amendment would be unduly prejudicial to Defendants and denying motions for leave to amend. *See* Docket No. 40-1 (Jan. 12, 2024 docket text order from M.D. Fla.); Docket No. 42-1 (Jan. 19, 2024 order from C.D. Cal.); Docket No. 42-2 (Jan. 19, 2024 order from N.D. Fla.); Docket No. 42-3 (Jan. 26, 2024 order from M.D. Ala.); Docket No. 42-4 (Jan. 17, 2014 docket text order from M.D. Fla.).

“Courts in this circuit recognize that futility arguments in the context of a motion to amend are functionally dispositive and present something of a conceptual difficulty when raised before a magistrate judge who, by statute, cannot ordinarily rule on dispositive motions.” *Local Spot, Inc. v. Lee*, No. 3:20-cv-00421, 2020 WL 7554214, at *4 (M.D. Tenn. Dec. 14, 2020) (citing *Durthaler v. Accounts Receivable Mgmt., Inc.*, No. 2:10-cv-1068, 2011 WL 5008552, at *4 (S.D. Ohio Oct. 20, 2011)). This is particularly true where the parties have raised – or intend to raise – the same or similar legal issues in dispositive motions to be decided by a district judge. *See Local Spot*, 2020 WL 7554214 at *4. (“Allowing Defendants’ substantive legal arguments to be addressed in a single decision is the most efficient course of action and will guard against inconsistent results in different procedural contexts.”).

Defendants have indicated that they will seek to dismiss Plaintiffs’ claims via a motion for summary judgment, at which point the parties’ arguments can be more appropriately decided by the district judge. (Docket No. 32 at ¶ K (“Sanofi also seeks leave to file an early motion for summary judgment on the statute of limitations, statute of repose, and the learned intermediary doctrine in the Jackson case.”).) Under these circumstances, “[a]llowing Defendants’ substantive legal arguments to be addressed in a single decision is the most efficient course of action and will guard against inconsistent results in different procedural contexts.” *Local Spot*, 2020 WL 7554214, at *4.¹⁶ The Court therefore declines to address the futility arguments in the context of an amendment motion.

¹⁶ To be clear, the undersigned expresses no opinion on the merits of the parties’ arguments, including implicitly by denying Plaintiffs’ motion to amend.

IV. CONCLUSION

For these reasons, Plaintiff Sylvia Jackson's motion for leave to amend (Case No. 3:23-cv-00553, Docket No. 35) is **DENIED** and Plaintiff Faye Byrd's motion for leave to amend (Case No. 3:23-cv-01137, Docket No. 30) is **DENIED**.

It is SO ORDERED.

A handwritten signature in black ink, appearing to read "Barbara D. Holmes", written over a horizontal line.

BARBARA D. HOLMES
United States Magistrate Judge